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10/695,848

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EXAMINER

MEHTA, BHISMA

ART UNIT

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3767

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/695,848 | <b>Applicant(s)</b><br>FEREK-PETRIC, BOZIDAR |  |
|                              | <b>Examiner</b><br>BHISMA MEHTA      | <b>Art Unit</b><br>3767                      |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 46-48, 50-52, 54-59 and 61-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46-48, 50-52, 54-59, and 61-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 46-48, 50-52, and 54-56 are objected to because of the following informalities: It appears that there is an error with the recitation of “from about 50 milliseconds to about 200 microseconds” in line 13 of claim 46. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 46-48, 50-52, 56, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst et al (U.S. Patent No. 6,733,485) in view of Houben et al (U.S. Patent No. 6,261,280). Whitehurst et al disclose a method of treating a cancerous tumor via a wholly-implantable medical device comprising a wholly-implantable electroporation device (150) which includes a drug reservoir (140) and operative control circuitry (145) both disposed within a housing (150). Whitehurst et al disclose implanting the wholly-implantable electroporation device (150) wholly within a body and delivering a drug to the body and proximate the tumor via a fluid conduit (141) coupled to the drug reservoir. Whitehurst et al also disclose delivering from the wholly-implantable electroporation device at least one electrical pulse across at least a portion

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of the cancerous tumor where the electric pulse produces an electric field from about 700 V/cm to about 1500 V/cm and has a pulse width of from about 50 ms to about 200 ms (lines 12-24 of column 8). In lines 37-62 of column 18, Whitehurst et al disclose sensing at least one biological parameter and providing a sense signal based on the biological parameter and conveying the biological parameter to the operative control circuitry, thus controlling the delivery of the at least one electrical pulse based on the sense signal. Whitehurst et al disclose a method of treating a cancerous tumor by electroporation where the impedance of the tissue being treated is measured and the delivery of the electrical pulses is adjusted based on the comparison of the impedance measured to a threshold impedance value and a measurement of impedance across a portion of the cancerous tumor is used to determine if the electroporation procedure needs to be continued (lines 37-49 of column 18 and lines 12-66 of column 19). In lines 36-47 of column 12, Whitehurst et al teach delivering the drug via an external drug delivery apparatus. Whitehurst et al disclose delivering the drug through a drug catheter (132). Whitehurst et al teach programming the electroporation device to deliver a particular therapy profile or algorithm which may occur after implantation (lines 24-49 of column 18).

Whitehurst et al disclose the method substantially as claimed. However, Whitehurst et al are silent to the step of detecting a qRs complex from an electrocardiogram and synchronizing the delivering of the electrical pulses with the qRs complex. Houben et al disclose a method for delivering stimulus or electrical pulses to generate an electric field and further teach detecting a qRs complex from an

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electrocardiogram during the delivery of the electrical pulses (lines 14-51 of column 4). Houben et al also teach synchronizing the delivery of the electrical pulses with the qRs complex (line 52 of column 4 to line 2 of column 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Whitehurst et al with the steps of detecting a qRs complex from an electrocardiogram and synchronizing the delivery of the electrical pulses with the qRs complex as taught by Houben et al as both Whitehurst et al and Houben et al disclose implantable devices that delivery electrical pulses and Houben et al teach that it is well known to monitor a patient's heart such that the delivery of the electrical pulses can be synchronized with the qRs complex to reduce cardiac interference (see abstract and lines 20-49 of column 5).

4. Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst et al and Houben et al as applied to claim 46 above, and further in view of Sterzer (U.S. Patent No. 5,386,837). Whitehurst et al and Houben et al disclose the method substantially as claimed. However, Whitehurst et al and Houben et al are silent to the step of increasing a temperature of the body near the tumor prior to delivering an electrical pulse. Sterzer discloses a method of treating a cancerous tumor such as a breast carcinoma by delivering a high frequency stimulus which increases the temperature at the site of the tumor (lines 45-68 of column 3), thus allowing the cells of the tumor to break down such that a chemotherapeutic drug can more easily enter the tumor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Whitehurst et al with the step of delivering

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a high frequency stimulus to increase the temperature near the tumor as Sterzer teaches that it is well known to increase the temperature of the tumor as it will provide for better delivery of the chemotherapeutic drug into the cells of the tumor, and thus, this will provide for better treatment of the tumor when the electrical pulses of the electroporation procedure of Whitehurst et al are applied.

5. Claims 58, 59, 63-65, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver (U.S. Patent No. 5,389,069) in view of Sterzer and in view of Houben et al. Weaver discloses a method for treating a cancerous tumor comprising implanting a wholly-implantable electroporation device in a body, delivering a drug (40) to the body, and delivering at least one electrical pulse across a portion of the tumor. Weaver also discloses the electroporation device as having at least one lead (20) with a therapy electrode (18) and delivering about one to about ten electrical pulses. Weaver discloses delivering electric pulses in the range of 100 volts to 1000 volts. Therefore, this is seen as delivering at least one electrical pulse producing an electric field strength of about 700 volts/cm to 1500 volts/cm as the actual electric field strength would be dependent on the relative location of the first and second electrode and of the size and location of the tumor being treated. Weaver also discloses delivering at least one electrical pulse of about 100 microseconds to about 1000 microseconds. The drug (40) is delivered via an external drug apparatus (42). In Figure 2, Weaver shows a drug catheter (54) coupled to a housing (62) of the electroporation device. Weaver teaches programming the electroporation device which may occur after implantation (lines 23-53 of column 4).

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Weaver discloses the method substantially as claimed. However, Weaver is silent to the step of increasing a temperature of the body near the tumor prior to delivering an electrical pulse. Sterzer discloses a method of treating a cancerous tumor such as a breast carcinoma by delivering a high frequency stimulus which increases the temperature at the site of the tumor (lines 45-68 of column 3), thus allowing the cells of the tumor to break down such that a chemotherapeutic drug can more easily enter the tumor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Weaver with the step of delivering a high frequency stimulus to increase the temperature near the tumor as Sterzer teaches that it is well known to increase the temperature of the tumor as it will provide for better delivery of the chemotherapeutic drug into the cells of the tumor, and thus, this will provide for better treatment of the tumor when the electrical pulses of the electroporation procedure of Weaver are applied. As to claim 59, Sterzer discloses a controlled rise of the temperature of the tumor and also allowing for a high therapeutic temperature which is below a safe temperature. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made that by increasing the temperature of the tumor by applying the high frequency stimulus as taught by Sterzer would require sensing the temperature such that the temperature of the treated tumor can be kept at a safe level.

Additionally, Weaver is silent to the step of detecting a qRs complex from an electrocardiogram and synchronizing the delivering of the electrical pulses with the qRs complex. Houben et al disclose a method for delivering stimulus or electrical pulses to

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generate an electric field and further teach detecting a qRs complex from an electrocardiogram during the delivery of the electrical pulses (lines 14-51 of column 4). Houben et al also teach synchronizing the delivery of the electrical pulses with the qRs complex (line 52 of column 4 to line 2 of column 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Weaver with the steps of detecting a qRs complex from an electrocardiogram and synchronizing the delivery of the electrical pulses with the qRs complex as taught by Houben et al as both Weaver and Houben et al disclose implantable devices that delivery electrical pulses and Houben et al teach that it is well known to monitor a patient's heart such that the delivery of the electrical pulses can be synchronized with the qRs complex to reduce cardiac interference (see abstract and lines 20-49 of column 5).

6. Claims 61, 62, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver in view of Sterzer and in view of Houben et al as applied to claim 58 above, and further in view of Whitehurst et al. Weaver in view of Sterzer and in view of Houben et al disclose the method substantially as claimed. However, Weaver, Sterzer, and Houben et al are silent to the step of measuring impedance across a portion of the tumor and comparing the impedance to a threshold impedance value and to the specifics of the cancerous tumor being an osteosarcoma. Whitehurst et al disclose a method of treating a cancerous tumor by electroporation where the impedance of the tissue being treated is measured and the delivery of the electrical pulses is adjusted based on the comparison of the impedance measured to a threshold



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impedance value (lines 37-49 of column 18 and lines 12-66 of column 19). Also, in lines 57-67 of column 8, Whitehurst et al teach treating an osteosarcoma or bone sarcoma. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Weaver with the step of measuring the impedance of the tumor as taught by Whitehurst et al as Whitehurst et al teach that it is well known to use a measurement of impedance across a portion of the cancerous tumor to determine if the electroporation procedure needs to be continued. It also would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method of Weaver to treat an osteosarcoma as taught by Whitehurst et al as both Weaver and Whitehurst et al teach using electroporation to treat cancerous tumors which can include osteosarcomas.

### ***Response to Arguments***

7. Applicant's arguments with respect to claims 46-48, 50-52, 54-59, and 61-67 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767